

REMARKS

Claims 1, and 56-79 are pending. Claims 1 and 60-61 are canceled without prejudice to their renewal in a related application. Therefore, claims 56-59 and 62-79 are pending. Claims 56-59 and 76-77 are indicated as allowed. Claim 62 is amended in response to the Examiner's comments under the second paragraph of § 112. Claims 66 and 70 were amended to clarify that the claims are drawn to interactions between STAT protein dimers. Further minor claim amendments were made for consistency of style. No new matter is added by this amendment, and reconsideration of the claims in view of the amendments and following remarks is respectfully requested.

I. Finality of Restriction Requirement

Claims 1, 60, and 61 were formally cancelled without prejudice or disclaimer as drawn to non-elected subject matter.

II. Rejection Under the Second Paragraph of 35 U.S.C. § 112

Claims 62-75, 78, and 79 were rejected for indefiniteness. In response, the claims are amended in accordance with the Examiner's comments. This rejection may now be withdrawn.

III. Rejection Under 35 U.S.C. § 102(e)

A. Claims 66-75 were rejected as anticipated by McKnight et al. (US 5,710,266) on the basis that "McKnight et al. disclose an assay to determine drugs which modulate the dimerization of IL-4 STAT protein, which corresponds to STAT6." The rejection is premised on the Examiner's conclusion that the requirement that the association inhibited between dimers appears only in the preamble, and not in the body of the claim, and thus was not given patentable weight. This rejection is respectfully traversed.

Under the standard required for anticipation under § 102, the cited prior art reference is required to disclose every element of the claimed invention. A reference that merely contains substantially the same elements is insufficient to "anticipate" the claimed invention. Jamesbury Corp. v. Litton Industrial Products, Inc., 225 USPQ 253 (Fed. Cir. 1985). Similarly, a reference

that only broadly teaches the invention is also considered insufficient to establish anticipation. Kalman v. Kimberly-Clark Corp., 218 USPQ 781 (Fed. Cir. 1983). Further, an anticipatory reference must enable one skilled in the art to make the anticipated subject matter. PPG Industries, Inc. v. Guardian Industries Corp., 37 USPQ2d 1618 (Fed. Cir. 1996).

The analysis under § 102(e). The rejected claims are amended to clarify that the instant methods are directed to methods for identifying drugs that inhibit the ability of adjacent STAT dimers to interact. Applicants respectfully point out that the last sentence of claims 66 and 70 recites "wherein a test compound that decreases the association is identified as a drug that inhibits the interaction between adjacent activated STAT dimers." Accordingly, it is believed that the requirement recited in the body of the claim must be given patentable weight. However, in an effort to cooperate fully with the Examiner, the claims are amended to clarify that the interaction of interest is that between STAT protein dimers. Accordingly, it is believed that this rejection should be withdrawn.

B. Claims 66 –73 were rejected as anticipated under 35 USC § 102(e) by Leonard (US 6,265,160). This rejection is respectfully traversed as it may be applied to the amended claims.

The analysis under § 102(e). The above remarks are fully applicable to this rejection and are herein specifically incorporated by reference. The rejected claims are amended to clarify that the instant methods are directed to methods for identifying drugs that inhibit the ability of adjacent STAT dimers to interact. Thus, the instant invention is directed to identifying drugs that inhibit higher order interactions, e.g., those between dimers, whereas Leonard US 6,265,160 disclosing assays for determining agents which interfere with dimerization or heterodimerization of STAT3 or STAT5 proteins. Thus, Leonard is directed to assays for identifying agents which inhibit the ability of proteins, e.g., monomers, to form dimers, not to the interaction between dimers. Accordingly, it is believed that in light of the above remarks and amendments, this rejection may now be withdrawn.

Rejection Under 35 USC § 103(a)

Claims 66-75 were rejected as obvious over Leonard in view of Xu et al. further in view of Schreiber et al. This rejection is respectfully traversed as it may be applied to the amended

claims.

The Examiner has the initial burden of establishing a *prima facie* case of obviousness. A finding of obviousness under § 103 requires a determination of the scope and content of the prior art, the differences between the claimed invention and the prior art, the level of ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. Graham v. Deere, 383 US 1 (1966). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion that the combination be made. In re Stencel, 828 F2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987).

The analysis under §103(a). The above remarks in response to the rejections under §102(e) are fully relevant to this rejection, and are herein specifically incorporated by reference. Accordingly, it is believed that in light of the above remarks and amendments, this rejection should be withdrawn.

Conclusion

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions concerning this Amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,
KLAUBER & JACKSON

Valeta A. Gregg, Ph.D., J.D.
Registration No. 35,127

Continental Plaza
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 487-5800

Date: 4 / 11 / 2002



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57. (Amended) The method of [Claim] claim 56 wherein said first STAT protein is selected from the group consisting of STAT 1, STAT 2, STAT 3, STAT 4, STAT 5A, STAT 5B, and STAT 6.

58. (Amended) The method of [Claim] claim 56 wherein said second STAT protein is selected from the group consisting of STAT 1, STAT 2, STAT 3, STAT 4, STAT 5A, STAT 5B, and STAT 6.

59. (Amended) The method of [Claim] claim 56 wherein said first STAT protein and said second STAT protein are the same STAT protein.

62. (Amended Twice) A method for identifying a drug that enhances the ability of adjacent STAT protein dimers to interact comprising measuring the ability of a test compound to enhance the association of a fragment of a first STAT protein with a second STAT protein or a fragment of said second STAT protein [dimer];

wherein said fragment of said first STAT protein consists essentially of the N-terminal domain of said first STAT protein;

wherein said fragment of said second STAT protein comprises the N-terminal domain of said second STAT protein;

wherein the association is dependent upon the N-terminal domain of said first STAT protein, and the N-terminal domain of said second STAT protein; and

wherein a test compound which enhances the association is identified as a drug that enhances the interaction between adjacent activated STAT dimers.

63. (Amended) The method of [Claim] claim 62 wherein said first STAT protein is selected from the group consisting of STAT 1, STAT 2, STAT 3, STAT 4, STAT 5A, STAT 5B, and STAT 6.

64. (Amended) The method of [Claim] claim 62 wherein said second STAT protein is selected

from the group consisting of STAT 1, STAT 2, STAT 3, STAT 4, STAT 5A, STAT 5B, and STAT 6.

65. (Amended) The method of [Claim] claim 62 wherein said first STAT protein and said second STAT protein are the same STAT protein.

66. (Amended Once) A method for identifying a drug that inhibits the ability of adjacent STAT protein dimers to interact comprising measuring the ability of a test compound to inhibit the association of a first STAT protein dimer or a fragment of said first STAT protein dimer with a second STAT protein dimer or a fragment of said second STAT protein dimer;

wherein said fragment of said first STAT protein dimer comprises the N-terminal domain of [said] a first STAT protein;

wherein said fragment of said second STAT protein dimer comprises the N-terminal domain of [said] a second STAT protein;

wherein the association is dependent upon the N-terminal domain of said first STAT protein, and the N-terminal domain of said second STAT protein; and

[whereas] wherein a test compound that decreases the association is identified as a drug that inhibits the interaction between adjacent activated STAT dimers.

70. (Amended Once) A method for identifying a drug that inhibits the ability of adjacent STAT protein dimers to interact comprising measuring the ability of a test compound to inhibit the association of a fragment of a first STAT protein dimer with a second STAT protein or a fragment of said second STAT protein dimer;

wherein said fragment of said first STAT protein dimer consists essentially of the N-terminal domain of [said] a first STAT protein;

wherein said fragment of said second STAT protein dimer comprises the N-terminal domain of [said] a second STAT protein;

wherein the association is dependent upon the N-terminal domain of said first STAT protein dimer, and the N-terminal domain of said second STAT protein dimer; and

[whereas] wherein a test compound that decreases the association is identified as a drug that inhibits the interaction between adjacent activated STAT dimers.